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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/455,975	05/31/1995	JEFFREY S. RUBIN	40399/299/NI	9287

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EXAMINER

SAOUD, CHRISTINE J

ART UNIT PAPER NUMBER

1647

DATE MAILED: 03/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/455,975

Applicant(s)

RUBIN et al.

Examiner

Christine Saoud

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 13, 2001
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-45, 57-62, 64-86, 88, 89, 91-109, 111-119, 132, 133, 136, ~~137~~ ^{137, 140-147, 149-193} is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38-45, 57-62, 64-86, 88, 89, 91-109, 111-119, 132, 133, 136, 137, ~~138~~ ^{140-147, 149} is/are allowed.
- 6) ☒ Claim(s) 150-174 and 177-193 is/are rejected.
- 7) ☒ Claim(s) 175 and 176 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 33
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Claims 49-55, 63, 87, 90, 110, 121-131, 134-135, 138-139 and 148 have been canceled, claims 66, 76-77 have been amended, and claims 150-193 have been added as requested in the amendment of paper #30, filed 17 April 2001. Claims 38-45, 57-62, 64-86, 88-89, 91-109, 111-119, 132-133, 136-137, 140-147, 149-193 are pending in the instant application.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
4. Applicant's arguments filed 13 December 2001 have been fully considered but they are not deemed to be persuasive.

Claim Objections

5. Claim 152 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The recitation of "wherein the DNA is expressed in an isolated host

cell fails to further limit the method of claim 150, because expression of the DNA is already recited in claim 150.

6. Claim 175 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 73. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). It is noted that claim 73 indicates that the polypeptide is either glycosylated or non-glycosylated, however, as claim 175 does not indicate as to which, it would also encompass both forms. Claim 176 is to the polypeptide further comprising an N-terminal methionine, however, this limitation is also included in claim 76 which depends from 73, therefore, claim 176 is substantially duplicative of claim 76.

7. Claim 178 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The recitation of "wherein the DNA is expressed in an isolated host cell fails to further limit the method of claim 177, because expression of the DNA is already recited in claim 177.

Claim Rejections - 35 USC § 112

8. Claims 155-162, 177-193 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to methods of stimulating epithelial cells by administering KGF or segments of KGF, "wherein said polypeptide has mitogenic activity". However, the activity limitation does not apply to the "segments" which are claimed. In order to practice the methods as claimed, the segments must also possess biological activity. Therefore, the recitation of "segments" does not provide sufficient structure to enable the claimed method because a segment could encompass a peptide with as few as 2 amino acids which would not be expected to be useful for stimulating epithelial cells. This ground of rejection could be avoided if the claims were amended to recite "wherein the segment has mitogenic activity", since such activity is already possessed by the recited polypeptide.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 150-174 and 177-193 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 150 recites "a DNA encoding a polypeptide having a sequence comprising amino acids 32-194 of Figure 7". A polypeptide may have a sequence, but the sequence does not comprise amino acids because a sequence is merely a representation of structure on paper. The claim could be clarified by the recitation of "encoding a polypeptide comprising amino acids 32-194 of Figure 7".

Claim 152 was found to be objected to (see above). Claim 154 could be rewritten such that it depends from claim 150 and recites "wherein said DNA is expressed in a bacterial cell, a fungal cell, a mammalian cell or an insect cell".

Claims 155, 163, 167, 171, 177, 181 and 190 recite "polypeptide comprising the amino acid sequence 32 to 194 of Figure 7" or "segment of the amino acid sequence 32-194". This does not appear to make sense in reference to amino acids and sequence as a single entity in the current order, especially since there is no "sequence 32 to 194". The claim could be clarified by the recitation of "polypeptide comprising amino acids 32 to 194 of Figure 7". In correcting these claims, the claims should then recite "of said polypeptide" rather than "said sequence".

Allowable Subject Matter

11. Claims 38-45, 57-62, 64-86, 88-89, 91-109, 111-119, 132-133, 136-137, 140-147, 149 are allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 7AM to 3PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

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Official papers filed by fax should be directed to (703) 308-4556. If this number is out of service, please call the Group receptionist for an alternate number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud